

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL 2327</b>  <b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>
<b>THIS DOCUMENT RELATES TO:  WAVE 2 CASES</b>	

**RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO STRIKE  
DR. SHELBY F. THAMES' SUPPLEMENTAL REPORTS OR, IN THE  
ALTERNATIVE, FOR LEAVE TO FILE A *DAUBERT* MOTION**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this response to Plaintiffs' Motion to Strike Dr. Shelby F. Thames' Supplemental Reports or, in the alternative, for Leave to File a *Daubert* Motion Based on the Flawed Methodology Employed Therein ("Motion"). *See* [ECF No. 2882 ("Mot.")]. This Response applies to the cases identified in Exhibit A to Plaintiffs' Motion.

**INTRODUCTION**

Ethicon timely disclosed Dr. Thames as a general expert, and timely served on Plaintiffs Dr. Thames's initial expert report June 3, 2016. *See* Mot. Ex. D [ECF No. 2882-4]. Thereafter, Ethicon disclosed two supplemental reports prepared by Dr. Thames in response to Plaintiffs' expert's claims: "Intentional Oxidation of Prolene Mesh Supplemental Report of Dr. Shelby F. Thames" dated August 8, 2016, and "Intentional Oxidation of Prolene Mesh – Part 2" dated September 28, 2016 (collectively "Supplemental Reports"). *See* Mot. Ex. B [ECF No. 2882-2]; Mot. Ex. C [ECF No. 2882-3].

As Dr. Thames explained in his Supplemental Reports, Plaintiffs have argued “that the explant cleaning protocol . . . use[d] during the examination of explant samples” as described in his initial expert report “in some way, ‘destroys oxidation carbonyls’ should they exist.” Mot. Ex. B at 1. Plaintiffs first raised this argument—without any scientific support—in their Wave 1 *Daubert* briefing. *See* Mem. in Supp. of Pls.’ Mot. to Exclude Certain Opinions of Dr. Shelby Thames, at 8-10 [ECF 2042].

In response to Plaintiffs’ speculative assertions, Dr. Thames developed a test of his cleaning protocol “[t]o prove unequivocally this does not occur.” Mot. Ex. B at 1. Specifically, Dr. Thames tested his cleaning protocol by “intentionally oxidiz[ing] via exposure to ultraviolet light” “an exemplar Prolene mesh” for 500 hours. *Id.* Dr. Thames then processed the oxidized Prolene mesh using steps from his cleaning protocol, and evaluated it to determine if the process removed oxidation carbonyls. *Id.* at 12.

Although Dr. Thames had not completed his testing when Ethicon served his August 8, 2016, supplemental report, he expressly stated that “[t]he oxidized Prolene exemplar [was] currently being processed through the cleaning steps of Figure 1, and that data will be reported when complete.” *Id.* On September 28, 2016, Ethicon served Dr. Thames’s second supplemental report providing the completed data set to Plaintiffs. *See* Mot. Ex. C.

Plaintiffs now ask the Court to strike Dr. Thames’s Supplemental Reports on the grounds that they were untimely served. *See generally* Pls.’ Mot. The Court should deny Plaintiffs’ Motion because the disclosure of Dr. Thames’s Supplemental Reports was justified, and in any event, harmless to Plaintiffs in this litigation.

## ARGUMENT

### **I. The Court Should Deny Plaintiffs’ Motion To Strike Dr. Thames’s Second Supplemental Report.**

Federal Rule of Civil Procedure 37(c) provides that “[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless.” In determining whether to exclude an expert’s supplemental report pursuant to Rule 37, this Court has consistently applied the five-factor test articulated by the Fourth Circuit in *Hoyle v. Freightliner, LLC*, 650 F.3d 321 (4th Cir. 2011). *See, e.g., Baugher v. Ethicon, Inc., et al.*, No. 2:12-cv-01053, 2016 WL 5871002, at \*1 (S.D. W. Va. Oct. 6, 2016) (providing defendants additional time to depose plaintiffs’ expert based on a late-disclosed report); *Wilkerson v. Boston Sci. Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at \*19 (S.D. W. Va. May 5, 2015) (declining to exclude amended report of Plaintiffs’ expert). Per *Hoyle*, a court should consider the following factors in determining whether to sanction a party under Rule 37(c):

(1) the surprise to the party against whom the witness was to have testified; (2) the ability of the party to cure that surprise; (3) the extent to which allowing the testimony would disrupt the trial; (4) the explanation for the party’s failure to name the witness before trial; and (5) the importance of the testimony.

650 F.3d at 329.

As discussed below, there is no basis for striking Dr. Thames’s Supplemental Reports in this litigation under *Hoyle* because it did not “surprise” Plaintiffs, the opinions are important to Ethicon’s ability to defend against Plaintiffs’ claims, and no trial dates have been set in this litigation. Therefore, any harm that may have been done to Plaintiffs “may be easily remedied by

allowing them to have additional time to depose” Dr. Thames and allow for supplemental *Daubert* briefing. *Baughner*, 2016 WL 5871002, at \*2.

**A. Exclusion of Dr. Thames’s Supplemental Reports is not warranted under the *Hoyle* test.**

Application of the *Hoyle* factors demonstrates that the Court should deny Plaintiffs’ motion to strike Dr. Thames’s Supplemental Reports. First, Dr. Thames’s Supplemental Reports were no surprise to Plaintiffs. Indeed, Dr. Thames conducted the testing discussed in his Supplemental Reports to rebut to arguments first raised by Plaintiffs in their *Daubert* briefing. For this reason, Plaintiffs cannot claim that Dr. Thames’s testing was a surprise; indeed, Plaintiffs should have expected that he would seek to rebut their unsupported assertions.

This Court has previously found the element of surprise lacking where a party’s late disclosure was elicited by arguments or evidence advanced by the other party. *See Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 573 (S.D. W. Va. 2014) (finding no surprise, but excluding supplemental report because trial was looming and the report was not crucial to the plaintiff’s case). In *Tyree*, after the plaintiff’s disclosure of an expert’s report that “did not include conclusions based on a physical examination,” and the defendant disclosed its expert’s “opinions related to the examination of [the plaintiff.]” *Id.* Finding that the defendant “should have expected that [plaintiff] might choose to rebut those opinions” based on its own disclosure, the Court held that the defendant’s claim of surprise was “unfounded.” *Id.*

Here, it cannot be said that Dr. Thames’s Supplemental Reports were a surprise to Plaintiffs. Significantly, Plaintiffs make no such argument here. *See* Motion at 2-3. Similarly, because there was no surprise, and therefore nothing to cure, the second factor also weighs against exclusion.

Turning to the third factor, there are no trial dates set for any of the Wave 2 cases identified in Exhibit A to Plaintiffs' Motion. Thus, Dr. Thames's testimony based on this testing does not present any risk of disrupting any trial.

As to the fourth factor, Ethicon notes that Dr. Thames performed the testing reported in his Supplemental Reports to rebut Plaintiffs' arguments first articulated in their Wave 1 challenge to Dr. Thames's opinions. *See* Mem. in Supp. of Pls.' Mot. to Exclude Certain Opinions of Dr. Shelby Thames, at 8-10 [ECF 2042]. Ethicon served the first supplemental report on August 8, 2016, at the conclusion of Dr. Thames's initial testing, and the second supplemental report on September 28, 2016, as soon as Dr. Thames completed his testing and compiled the data.

Finally, with respect to the fifth factor, while the opinions contained in the Supplemental Reports are not substantially different from those contained in his initial expert report, they are important to Ethicon's defense against Plaintiffs' claims. As discussed in detail in Dr. Thames's initial expert report, Dr. Thames's testing of numerous mesh explants provides reliable and repeatable scientific evidence rebutting Plaintiffs' allegations that the Prolene in Ethicon mesh products oxidizes and degrades *in vivo*. *See* Mot. Ex. D, at 109-128. In response to this compelling testing, Plaintiffs claimed—without any scientific support—that Dr. Thames's cleaning protocol eliminates evidence of oxidation. Thus, the testing described in both of Dr. Thames's supplemental reports is significant in that it disproves Plaintiffs' speculation regarding the validity of his underlying test results.

Thus, Dr. Thames's testing is a proper rebuttal to Plaintiffs' assertions, which Plaintiffs certainly should have anticipated. In other words, Dr. Thames's Supplemental Reports were not

the result of inadequate or incomplete preparation, but rather a good-faith attempt to rebut Plaintiffs' challenges to the opinions identified in his initial expert report.

**B. Ethicon does not object to additional time to depose Dr. Thames regarding his Supplemental Reports and supplemental *Daubert* briefing.**

Any harm done to Plaintiffs by Dr. Thames's Supplemental Reports "may be easily remedied by allowing them to have additional time to depose Dr. [Thames]" and setting a schedule for supplemental *Daubert* briefing limited to the Supplemental Reports and opinions contained therein. *Baughner*, 2016 WL 5871002, at \*2. Ethicon respectfully submits that this approach is appropriate under these circumstances.

The Court has previously taken this course of action even when an expert's supplemental report advanced wholly new opinions, entirely distinct from those disclosed earlier. *Id.* ("The supplemental report is twenty-two pages long, whereas the original report is merely three pages long. Also, the supplemental report recommends that the plaintiff's TVT-O device be removed, but the original report recommended that the device stay in place. Finally, the supplemental report documents a number of alleged symptoms the plaintiff suffers that were not offered in the original report."). The results here should be no different, particularly since Dr. Thames's Supplemental Reports merely present the completed results of his test, and not any new opinions.<sup>1</sup>

**C. This Court's previous exclusions of supplemental reports are distinguishable.**

Although this Court has previously stricken or excluded supplemental expert reports pursuant to Rule 37(c), those cases involved the disclosure of new opinions in cases approaching

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<sup>1</sup> Plaintiffs argue that Dr. Thames's testing is irrelevant and unreliable in this litigation. Pls.' Mot. at 3-4. Although Plaintiffs' arguments are meritless, Ethicon agrees that any such arguments should be addressed through supplemental *Daubert* briefing.

a trial date. For example, Plaintiffs point the Court to its decision to exclude Dr. Rosenzweig's fourth supplemental expert report in *Huskey v. Ethicon*. See Pls.' Mot. at 2. However, the Court's ruling in *Huskey* was made at a pretrial conference with a trial looming. Indeed, the Court clearly explained that it excluded Dr. Rosenzweig's supplemental report because it contained new opinions disclosed on the eve of trial. See Mot. Ex. E at 4:21-5:6 [ECF No. 2882-5].

No such circumstances exist with respect to Dr. Thames's Supplemental Reports, and the Court's decision in *Huskey* is therefore inapposite. Accordingly, the Court should deny Plaintiffs' motion.

### CONCLUSION

For these reasons, the Court should deny Plaintiffs' Motion to Strike Dr. Shelby F. Thames' Supplemental Report.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on October 20, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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